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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,964	04/15/2004	Kenneth T. Heruth	1023-360US01	8232
28863	7590	04/26/2006	EXAMINER	
SHUMAKER & SIEFFERT, P. A. 8425 SEASONS PARKWAY SUITE 105 ST. PAUL, MN 55125			DRYDEN, MATTHEW DUTTON	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 04/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/825,964	<b>Applicant(s)</b> HERUTH ET AL.	
	<b>Examiner</b> Matthew D. Dryden	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 April 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-68 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/06, 9/05, 4/05</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

Claim 40 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claim recites the limitation of a means for generating at least one signal and it is unclear what the means for doing this step is.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5-8, 10, 11, 13, 19-21, 23-26, 28, 29, 34, 35, 38-44, 46-49, 53-56, 59, 62, 63, and 65-67 are rejected under 35 U.S.C. 102(e) as being anticipated by Poezevera et al (6773404).

Regarding claim 1, Poezevera discloses a method comprising:

monitoring a plurality of physiological parameters of a patient (see Columns 2-3, lines 65-62),

determining a value of a sleep metric that indicates a probability of the patient being asleep based on the physiological parameters (see Columns 3-4, lines 63-11).

Regarding claim 2, see Column 3, lines 5-8, also the minute ventilation sensor as predominantly used by Poezevera can be viewed as a respiration rate.

Regarding claim 3, see Column 3, lines 7-8.

Regarding claim 5, see Column 4, lines 4-6.

Regarding claim 6, the sleep metric values could be the values taken for both the minute ventilation and the activity sensor, and a multitude of values are taken by each of these sensors.

Regarding claim 7, once the plurality of signals are gathered for the physiological parameters they are averaged to form an overall sleep metric and compared with a threshold value to determine the sleep status of the individual (see Columns 3-4, lines 63-28).

Regarding claim 8, see rejection of claim 7 above.

Regarding claim 10, see Column 4, lines 4-7.

Regarding claim 11, the method of Poezevera teaches to compare a sleep value with a plurality of thresholds to determine a sleep state of the individual (see Column 4, lines 4-27).

Regarding claim 13, the threshold value of Poezevera is selected by the user.

Regarding claim 19, Poezevera discloses a system comprising:

a plurality of sensors, generating a signal as a function of at least one physiological parameter (see Columns 2-3, lines 65-62),

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a processor that monitors a plurality of physiological parameters of the patient based on the signals output by the sensors, and is capable of determining a value of sleep metric that indicates a probability of the patient being asleep based on the physiological parameters (see Columns 7-8, lines 44-8).

Regarding claim 20, see Column 3, lines 5-8, also the minute ventilation sensor as predominantly used by Poezevera can be viewed as a respiration rate.

Regarding claim 21, see Column 3, lines 7-8.

Regarding claim 23, the processor of Poezevera is capable of determining a mean value and determining a sleep metric therefrom (see Columns 7-8, lines 44-8, Columns 3-4, lines 63-28).

Regarding claim 24, the sleep metric values could be the values taken for both the minute ventilation and the activity sensor, and a multitude of values are taken by each of these sensors, and the processor of Poezevera is capable of determining these values.

Regarding claim 25, the processor of the current invention performs all of the methods discussed in the summary and disclosure of the invention, once the plurality of signals are gathered for the physiological parameters they are averaged to form an overall sleep metric and compared with a threshold value to determine the sleep status of the individual (see Columns 3-4, lines 63-28).

Regarding claim 26, see rejection of claim 25.

Regarding claims 28 and 29, the memory of the processor stores the threshold value and the processor compares the value to a threshold value to determine the sleep

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status of the patient, and the memory is capable of storing a plurality of threshold values and the processor is capable of comparing the values of the sleep metric with the threshold values to determine the sleep state of the patient (see Columns 7-8, lines 44-8 and Columns 3-4, lines 63-28).

Regarding claims 34 and 35, see column 4, lines 65-67.

Regarding claim 38, see Column 4, lines 65-67.

Regarding claim 39, Poezevera discloses a system comprising:

a plurality of sensors, generating a signal as a function of at least one physiological parameter (see Columns 2-3, lines 65-62), which are the means for monitoring a plurality of physiological parameters,

a processor that monitors a plurality of physiological parameters of the patient based on the signals output by the sensors, and is capable of determining a value of sleep metric that indicates a probability of the patient being asleep based on the physiological parameters (see Columns 7-8, lines 44-8), which can be viewed as the means for determining a value of sleep metric.

Regarding claim 40, although not specifically mentioned in the specification the means for generating the signal is viewed to be an analog to digital converter (see Column 8, lines 1-9), and the means for monitoring comprises means for monitoring the physiological parameters based on the signal.

Regarding claims 41-43, the processor of Poezevera is capable of performing these functions and has means for accomplishing these functions, see rejections of claims 24, 25, and 28.

Regarding claim 44, see Column 3, lines 16-21, and column 4, lines 65-67, wherein the processor is capable of controlling the delivery of the therapy based on the determination of whether the patient is asleep.

Regarding claim 46, Poezevera discloses a method comprising:  
monitoring a physiological parameter of a patient via an implantable medical device (see Columns 3-4, lines 4-67),  
determining whether the patient is asleep based on the physiological parameter (see Columns 3-4, lines 63-11).

Regarding claim 47, the device of Poezevera also monitors the activity level (see Column 4, lines 11-28), also the plurality of physiological parameters can be just the multitude of values taken from the first physiological parameter.

Regarding claim 48, the averaging of the values of the physiological value can be viewed as the sleep metric, which is then compared with a threshold values, and determines whether or not the patient is asleep (see Columns 3-4, lines 63-11).

Regarding claim 49,  
the sleep metric value could be the values taken for both the minute ventilation and the activity sensor, and a multitude of values are taken by each of these sensors and averaged,

once the plurality of signals are gathered for the physiological parameters they are averaged to form an overall sleep metric and compared with a threshold value to determine the sleep status of the individual,

regarding the comparison of the values (see Column 4, lines 4-27).

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Regarding claim 53, Poezevera discloses a system comprising:  
a sensor to generate a signal as a function of a physiological parameter of a patient (see Columns 2-3, lines 65-8),  
an implantable medical device that includes a processor to monitor the parameter (see Column 4, lines 65-67, and columns 7-8, lines 44-9).

Regarding claim 54, see Columns 7-8, lines 44-9, and columns 3-4, lines 63-28.

Regarding claim 55, the implantable medical device comprises a memory capable of storing a threshold values (see Column 7, lines 63-67),  
and the processor is capable of determining a value of a sleep metric that indicates a sleep state of the patient based on the plurality of physiological parameters, compares the value to a threshold value, and determines if the person is asleep (see Columns 7-8, lines 44-9, Columns 3-4, lines 4-67).

Regarding claim 56, see rejection of claim 49 above.

Regarding claim 59, see Column 4, lines 65-67.

Regarding claim 62, see Column 4, lines 65-67, and these devices can be used as a neurostimulator.

Regarding claim 63, the disclosure of Poezevera discloses a processor having instructions stored on memory so that the desired methods of invention can be performed (see Columns 7-8, lines 44-9), the instructions are stored in memory which is a computer readable medium, for the method discussed in claim 63 see rejection of claim 1.

Regarding claim 65, see rejection of claims 6 and 7.



Regarding claim 66, see rejection of claim 10.

Regarding claim 67, see rejection of claim 11.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 22, and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poezevera in view of Kowallik et al (6752766). Poezevera discloses the claimed device and method except for the method comprising a step of determining the variability of a physiological parameter and determining a sleep value based on the variability. Kowallik teach it is known to provide a method a device and method that is capable of detecting the variability of a respiration rate so that the signals and parameter can be analyzed to characterize the stage of sleep that the individual is in (see Column 2, lines 21-52). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device and method of Poezevera with a method step of determining the variability of a physiological parameter and determining a sleep value based on the variability, as taught by Kowallik et al, so that the signals and parameter can be analyzed to characterize the stage of sleep that the individual is in.

Claims 9 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poezevera in view of Remmers et al (5645053). Poezevera discloses the claimed

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method and device except for using a weighting factor to determine the sleep metrics. Remmers et al teach it is known to use a weighting value with a respiration rate (one of the physiological parameters of the applicant) which results in quicker adaptation of the threshold detection mechanism (see Column 11, lines 13-17). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and device of Poezevera to include using a weighting factor to determine the sleep metrics, as taught by Remmers et al, which results in quicker adaptation of the threshold detection mechanism.

Claims 12, 30, and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poezevera in view of Rapoport et al (5732696). Poezevera discloses the claimed invention except for the device comprising a method and device for determining whether the patient is in one of a rapid eye movement sleep state or a non-rapid eye movement sleep state. Rapoport et al teach it is known to provide a method and processor that determines whether the patient is in a rapid eye movement sleep state or a non-rapid eye movement sleep state, to further characterize there sleep state which is useful in determining when to apply a therapy and gives insight into how soon the patient will awake (see Column 5, lines 5-39). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Poezevera with a method and device for determining whether the patient is in one of a rapid eye movement sleep state or a non-rapid eye movement sleep state, as taught by Rapoport et al, to further characterize there sleep state which is useful in determining when to apply a therapy and gives insight into how soon the patient will awake.

Claims 14-18, 32, 33, 36, 37, 45, 50, 51, 52, 57, 58, 60 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poezevera in view of Cho et al (2002/0193697). Poezevera discloses the claimed method except for the method comprising controlling delivery of therapy to the patient based on the determination of whether the patient is asleep. Cho et al teach it is known to provide a step of delivering therapy to a patient based on the determination of a sleep metric (in this case apnea hypopnea index) so that the efficacy of the therapy can be monitored to see if the correct form of therapy is being used, while the patient is still asleep, or if a new therapy should be used (see paragraphs 0030, 0031, 0046, and 0048). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device and method of Poezevera with a method of controlling delivery of therapy to the patient based on the determination of whether the patient is asleep, as taught by Cho et al, controlling delivery of therapy to the patient based on the determination of whether the patient is asleep. Also, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Poezevera with a step of determining the efficacy of the therapy, as taught by Cho et al, to determine if the therapy is working or to determine if a new therapy needs to be used.

Regarding claims 15, 33, 45, 51, and 58 Poezevera discloses the claimed method and system except for storing the information of when the patient is asleep with the processor. Cho et al teach it is known to provide a processor and to store values of sleep events so that the values can be analyzed later to provide a diagnosis for a

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specific form of therapy for the patient (see paragraphs 0053, 0054, 0055). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device and method of Poezevera with a step of storing the information of when the patient is asleep with the processor, as taught by Cho et al, so that the values can be analyzed later to provide a diagnosis for a specific form of therapy for the patient.

Regarding claims 17 and 18, the therapy delivered in Cho et al can be viewed as a form of neurostimulation and pain therapy.

Regarding claims 36 and 60, Poezevera discloses the claimed invention except for the implantable device being coupled to the sensor via a lead. Cho et al teach it is known to attach a sensor to an implantable medical device via a lead (see paragraph 0027), to allow for control of both the implantable medical device and the sensors under the same processor. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Poezevera with a sensor being coupled to an implantable medical device, as taught by Cho et al, to allow for control of both the implantable medical device and the sensors under the same processor.

Regarding claims 37 and 61, Poezevera discloses the claimed invention except for the implantable device being coupled wirelessly to the sensor. Cho et al teach it is known to attach a sensor to an implantable medical device wirelessly (see paragraph 0033) so that the sensor can be placed in a different region than that of the implantable medical device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Poezevera with an implantable

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device being coupled wirelessly to the sensor, as taught by Cho et al, so that the sensor can be placed in a different region than that of the implantable medical device.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Poezevera in view of Goldberg et al (6296606). Poezevera discloses the claimed invention except for the system comprising a user interface, where the user selects the threshold. Goldberg et al teach it is known to provide a medical system with a user interface that allows a caregiver to select a predetermined threshold (see Column 24, lines 6-7), so that the user can select a desired threshold based on their specifications. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Poezevera to include a user interface that allows for selecting a threshold, as taught by Goldberg et al, so that the user can select a desired threshold based on their specifications.

#### ***Prior Art***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Pat. No. 4,297,685 Brainard, II discloses an apparatus and method for sleep detection

U.S. Pat. No. 6,878,121 Krausman et al disclose a sleep scoring apparatus and method

U.S. Pat. No. 6,514,218 Yamamoto discloses a posture detecting device and breathing function-measuring device.


**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew D. Dryden whose telephone number is (571) 272-6266. The examiner can normally be reached on Monday-Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MDD

  
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